

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

THE TRUSTEES OF THE UNIVERSITY OF  
PENNSYLVANIA,

Plaintiff,

v.

ELI LILLY AND COMPANY,  
IMCLONE LLC and  
BRISTOL-MYERS SQUIBB COMPANY,

Defendants.

Civil Action No. 2:15-cv-06133-WB

**DEFENDANTS' ANSWER AND COUNTERCLAIMS**

Defendants Eli Lilly and Company (“Lilly”), ImClone LLC (“ImClone”), and Bristol-Myers Squibb Company (“BMS,” collectively “Defendants”) hereby answer the Complaint for Patent Infringement and Jury Demand (“Complaint”) filed by The Trustees of the University of Pennsylvania (“Penn”) and counterclaim as follows:<sup>1</sup>

**THE PARTIES**

1. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 1 and therefore deny the allegations.

2. Defendants admit the allegations of paragraph 2.

3. Defendants admit the allegations of paragraph 3.

4. Defendants admit that ImClone LLC is a Delaware limited liability company.

Defendants admit that ImClone LLC previously was known as ImClone Systems Incorporated.

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<sup>1</sup> Defendants previously filed a Motion to Dismiss Improper Multiple Dependent Claims 32–40 of U.S. Patent No. 7,625,558. (D.I. 21.)

Defendants admit that ImClone is a wholly owned subsidiary of Eli Lilly and Company.

Defendants deny the remaining allegations of paragraph 4.

5. Defendants admit the allegations of paragraph 5.

6. Defendants admit the allegations of paragraph 6.

### **JURISDICTION AND VENUE**

7. The allegations of paragraph 7 express a legal conclusion to which no response is required. To the extent that a response is required, Defendants admit that the Complaint purports to state a cause of action for patent infringement arising under 35 U.S.C. § 271 et seq.

Defendants deny the remaining allegations of paragraph 7.

8. The allegations of paragraph 8 express legal conclusions to which no response is required. To the extent that a response is required, Defendants do not contest that this Court has subject matter jurisdiction over this action.

9. The allegations of paragraph 9 express legal conclusions to which no response is required. To the extent that a response is required, Lilly responds that, solely for the purposes of this action and solely for the claims asserted in the Complaint, it does not contest personal jurisdiction. Defendants deny the remaining allegations of paragraph 9.

10. The allegations of paragraph 10 express legal conclusions to which no response is required. To the extent that a response is required, ImClone responds that, solely for the purposes of this action and solely for the claims asserted in the Complaint, it does not contest personal jurisdiction. Defendants deny the remaining allegations of paragraph 10.

11. The allegations of paragraph 11 express legal conclusions to which no response is required. To the extent that a response is required, BMS responds that, solely for the purposes of this action and solely for the claims asserted in the Complaint, it does not contest personal jurisdiction. Defendants deny the remaining allegations of paragraph 11.

12. The allegations of paragraph 12 express legal conclusions to which no response is required. To the extent that a response is required, Defendants respond that, solely for the purposes of this action and solely for the claims asserted in the Complaint, Defendants do not dispute that venue is proper in this judicial district. Defendants deny the remaining allegations of paragraph 12.

### **BACKGROUND**

13. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 13 and on that basis deny the allegations.

14. Defendants admit that Exhibit A purports to be a copy of U.S. Patent No. 7,625,558 (“the ’558 patent”) entitled “Compositions and Methods of Treating Tumors.” Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 13 and on that basis deny the allegations..

15. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 15 and on that basis deny the allegations.

16. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 16 and on that basis deny the allegations.

17. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 17 and on that basis deny the allegations.

18. Defendants admit that ImClone and BMS entered into a Development, Promotion, Distribution, and Supply Agreement in September 2001. Defendants deny the remaining allegations of paragraph 18.

19. Defendants admit that the active ingredient in Erbitux is a monoclonal antibody known as cetuximab. Defendants admit that cetuximab inhibits dimerization of epidermal growth factor receptor (EGFR). Defendants deny the remaining allegations of paragraph 19.

20. Defendants deny the allegations of paragraph 20.
21. Defendants deny the allegations of paragraph 21.
22. Defendants admit that the FDA first approved Erbitux in 2004. Defendants admit that FDA approved Erbitux for treatment of locally or regionally advanced squamous cell carcinoma of the head and neck in combination with radiation therapy in 2006. Defendants deny the remaining allegations of paragraph 22.
23. Defendants deny the allegations of paragraph 23.
24. Defendants admit the allegations of paragraph 24.
25. Defendants deny the allegations of paragraph 25.
26. Defendants deny the allegations of paragraph 26.
27. Defendants admit that Lilly markets Erbitux in the United States. Defendants admit that Lilly sells Erbitux in the United States. Defendants deny the remaining allegations of paragraph 27.
28. Defendants deny the allegations of paragraph 28.
29. Defendants deny the allegations of paragraph 29.
30. Defendants deny the allegations of paragraph 30.
31. Defendants deny the allegations of paragraph 31.
32. Defendants admit that Erbitux has been sold in the United States with a label that includes instructions for use. Defendants admit that the Erbitux label has been approved by the United States Food and Drug Administration (“FDA”). Defendants admit that Erbitux is indicated in combination with radiation therapy for the initial treatment of locally or regionally advanced squamous cell carcinoma of the head and neck. Defendants deny that the March 2015

document cited in paragraph 32 is the current version of the Erbitux label. Defendants deny the remaining allegations of paragraph 32.

33. Defendants admit that Lilly's name appears on the current version of the Erbitux label. Defendants deny the remaining allegations of paragraph 33.

34. Defendants deny the allegations of paragraph 34.

35. Defendants admit that ImClone's name appears on the current version of the Erbitux label. Defendants admit that a trademark registered to ImClone appears on the current version of the Erbitux label. Defendants deny the remaining allegations of paragraph 35.

36. Defendants admit that ImClone employees have contributed content to the Erbitux label. Defendants deny the remaining allegations of paragraph 36.

37. Defendants deny the allegations of paragraph 37.

38. Defendants deny the allegations of paragraph 38.

39. Defendants deny the allegations of paragraph 39.

40. Defendants admit that some ImClone or Lilly employees were aware that the '558 patent had issued prior to the filing of the Complaint in this action. Defendants deny the remaining allegations of paragraph 40.

41. Defendants admit that U.S. Patent No. 6,417,168 was cited in the June 28, 2006 office action of the United States Patent and Trademark Office concerning U.S. Patent Application 10/661,881. Defendants deny the remaining allegations of paragraph 41.

42. Defendants admit that ImClone filed an opposition to European Patent application EP 99 907 641.6. Defendants admit EP 99 907 641.6 is a foreign counterpart to the '558 patent. Defendants admit that some ImClone or Lilly employees were aware that the '558 patent had issued in December 2009. Defendants deny the remaining allegations of paragraph 42.

43. Defendants admit that Penn and Lilly had discussions prior to the filing of the Complaint regarding the '558 patent. No agreement was reached. Defendants deny the remaining allegations of paragraph 43.

**First Cause of Action (Lilly's Infringement of the '558 Patent)**

44. Defendants incorporate by reference its responses to paragraphs 1–43.

45. Defendants admit that Lilly submits information to FDA for review and approval of the Erbitux label. Defendants admit that Erbitux is distributed with the FDA approved label. Defendants deny the remaining allegations of paragraph 45.

46. Defendants deny the allegations of paragraph 46.

47. Defendants deny the allegations of paragraph 47.

48. Defendants deny the allegations of paragraph 48.

49. Defendants deny the allegations of paragraph 49.

**Second Cause of Action (ImClone's Infringement of the '558 Patent)**

50. Defendants incorporate by reference its responses to paragraphs 1–49.

51. Defendants deny the allegations of paragraph 51.

52. Defendants deny the allegations of paragraph 52.

53. Defendants deny the allegations of paragraph 53.

54. Defendants deny the allegations of paragraph 54.

55. Defendants deny the allegations of paragraph 55.

**Third Cause of Action (BMS Infringement of the '558 Patent)**

56. Defendants incorporate by reference its responses to paragraphs 1–55.

57. Defendants deny the allegations of paragraph 57.

58. Defendants deny the allegations of paragraph 58.

59. Defendants deny the allegations of paragraph 59.

60. Defendants deny the allegations of paragraph 60.

61. Defendants deny the allegations of paragraph 61.

### **AFFIRMATIVE DEFENSES**

62. Further answering the Complaint, Defendants assert the following defenses without assuming any burden that they would not otherwise have, including without admitting or acknowledging that they bears the burden of proof as to any of them. Defendants reserve the right to amend their answer with additional defenses as further information is obtained.

#### **FIRST AFFIRMATIVE DEFENSE (NON-INFRINGEMENT)**

63. Defendants have not infringed any claim of the '558 patent, either directly or indirectly.

#### **SECOND AFFIRMATIVE DEFENSE (INVALIDITY)**

64. Each and every claim of the '558 patent is invalid or unenforceable for failing to meet one or more of the requisite conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

#### **THIRD AFFIRMATIVE DEFENSE (LACHES, WAIVER, EQUITABLE ESTOPPEL)**

65. The relief sought by Penn is barred in whole or in part under the doctrines of laches, waiver, and/or equitable estoppel.

#### **FOURTH AFFIRMATIVE DEFENSE (PROSECUTION HISTORY ESTOPPEL)**

66. Penn's claims are barred in whole or in part under the doctrines of prosecution history estoppel based on statements made during prosecution of the patent applications resulting in the '558 patent.

**FIFTH AFFIRMATIVE DEFENSE  
(LACK OF NOTICE)**

67. Penn's claims for damages prior to the date of notice to Defendants are barred for failure to provide notice of infringement as required by 35 U.S.C. § 287.

**SIXTH AFFIRMATIVE DEFENSE  
(FAILURE TO STATE A CLAIM)**

68. The Complaint fails to state a claim on which relief can be granted.

**COUNTERCLAIMS**

1. Lilly is an Indiana corporation having its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

2. ImClone is a Delaware limited liability company having its principal place of business at The Alexandria Center for Life Sciences, 450 East 29th Street, New York, NY 10016.

3. BMS is a Delaware corporation having its principal place of business at 345 Park Avenue, New York, New York 10154.

4. On information and belief, Penn is a Pennsylvania corporation having principal place of business at 3154 Walnut Street, Philadelphia, Pennsylvania 19104.

**JURISDICTION AND VENUE**

5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) and pursuant to 28 U.S.C. §§ 2201 and 2202.

6. This Court has personal jurisdiction over Penn because Penn is a Pennsylvania corporation with its principal place of business in Pennsylvania and because Penn has submitted to the jurisdiction of this Court by filing this lawsuit.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400. Penn has consented to venue by filing this lawsuit in this judicial district.



## **BACKGROUND FACTS**

8. On November 13, 2015, Penn filed the present lawsuit against Defendants, claiming infringement of the '558 patent. *See* Complaint.

9. In the Complaint, Penn alleges that it “is the owner and assignee of all right, title, and interest in and to the '558 Patent.” Complaint ¶ 15.

10. In the Complaint, Penn alleges that Defendants infringe the '558 patent. Complaint ¶¶ 44–61.

11. An actual, substantial and justiciable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Penn and Defendants concerning the infringement and validity of the '558 patent.

12. This controversy is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

### **COUNT I (DECLARATORY JUDGMENT OF NON-INFRINGEMENT)**

13. Defendants incorporate by reference paragraph 1–12 above.

14. Defendants do not and have not infringed, either directly or indirectly, any claim of the '558 patent.

15. Defendants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '558 patent.

16. This is an exceptional case under 35 U.S.C. § 285, entitling Defendants to an award of attorneys' fees incurred in connection with this action.

### **COUNT II (DECLARATORY JUDGMENT OF INVALIDITY)**

17. Defendants incorporate by reference paragraph 1–16 above.

18. Each and every claim of the '558 patent is invalid for failing to meet one or more of the requisite conditions of patentability specified in 35 U.S.C. §§ 101, 102, 103, 112 and/or 116.

19. Defendants are entitled to a declaratory judgment from this Court that each and every claim of the '558 patent is invalid.

20. This is an exceptional case under 35 U.S.C. § 285, entitling Defendants to an award of attorneys' fees incurred in connection with this action.

### **PRAYER FOR RELIEF**

Wherefore, Defendants respectfully request an Order and Judgment from this Court:

- a) declaring that Defendants do not and have not infringed any claim of the '558 patent;
- b) declaring that each and every claim of the '558 patent is invalid;
- c) adjudging this an exceptional case under 35 U.S.C. § 285 and granting Defendants an award of attorneys' fees, expenses, and costs;
- d) denying any and all relief sought by Penn in its Complaint; and
- e) granting such other relief as the Court deems proper.

### **DEMAND FOR JURY TRIAL**

Defendants hereby demand a trial by jury on all issues so triable.

Dated: January 15, 2015

Respectfully submitted.

/s/ Raymond B. Biagini

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Company, ImClone LLC, and Bristol-Myers  
Squibb Company*

**CERTIFICATE OF SERVICE**

I hereby certify that on January 15, 2016, I caused the foregoing *Defendants' Answer and Counterclaims* to be filed electronically through the Court's CM/ECF system. Copies of the foregoing have been served by electronic mail on the following counsel of record:

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Dated: January 15, 2016

/s/ Raymond B. Biagini  
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Raymond B. Biagini